

IPMS USER MANUAL

INAD Program
Management System (IPMS)



AADAP

Aquatic Animal Drug Approval
Partnership Program

www.aadapinad.com

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1. System Requirements

The IPMS should work in all web browsers with the exception of Internet Explorer 6.0. Recommended web browsers are the latest versions of Internet Explorer (8.0 or newer); Firefox (10.0); or Google Chrome.

A high speed internet connection is recommended. While the IPMS will work on a dial-up connection, individual page/screen response time will likely be considered problematic.

2. Establishing IPMS User Accounts

A. Account Types:

Monitor, create individual user accounts. Study monitor accounts should be created **before** facility accounts. During the establishment of a new facility account the facility's designated Study Monitor may then be selected from a drop-down menu, thereby effectively "linking" the facility with the appropriate Study Monitor. Pending review by the AADAP Office, each facility and Study Monitor will receive email notification with respect to the successful establishment of new user accounts.

[CHECK TO SEE IF YOUR FACILITY IS ALREADY ENROLLED](#)

USER ROLE

☒ Study Monitor ☐ Facility / Investigator

Figure 1.0

1. There are 2 separate accounts that must be established to complete participant enrollment in the IPMS. These accounts are:

(a) Facility/Investigator account, and (figure 1.0)

(b) Study Monitor account. (figure 1.0)

Note: Study Monitor accounts should be created before facility accounts.

During the process of creating these accounts, facility/investigator and study monitor accounts will be "linked."

2. It is important to remember that Investigators are responsible for the conduct of studies and the collection of complete and accurate data. Study Monitors are responsible for supervision of the trials, adherence of the Investigator to the Study Protocol, and inspection of the site. It is also important to note that the Investigator and Study Monitor cannot be the same person.

B. Creating a Facility/Investigator Account:

1. **General Account Information** (figure 2.0): When generating an account each Facility/Investigator must provide all required information as outlined in the Create Facility Account form. User Names and Passwords must meet the standards as set forth by the Federal Government. In addition to the basic facility information, you will also need to provide your current NPDES Number and FedEx shipping information. *Note: an email address can only be used for a single account. If you are an Investigator for one facility and a Study Monitor for another facility you will need two different emails.*

ACCOUNT INFORMATION *Indicates Required Field

USER NAME*: massive

PASSWORD*: *****

CONFIRM PASSWORD*: *****

CONTACT NAME*: Lyle Hebel

EMAIL ADDRESS*: lyle@massivestudios.info

GENERAL FACILITY INFORMATION *Indicates Required Field

INVESTIGATOR FIRST NAME*: Lyle

INVESTIGATOR LAST NAME*: Hebel

Password requirements:

- Letters or numbers only
- At least 12 characters
- At least one upper-case character
- At least one lower-case character
- At least one number

figure 2.0

2. **Facility Already Enrolled** (figure 3.0): Each Facility/Investigator is allowed only a single AADAP INAD account. If your facility is already enrolled you will not be able to create a new (second) account. All enrolled facilities are listed in alphabetical order in the IPMS (a). If you see your facility on the list, an individual has already enrolled your facility into the program.

Establishing New User Accounts

Participation in the INAD PROGRAM MANAGEMENT SYSTEM requires that each facility (i.e., Investigator), as well as each facility's designated Study Monitor, create individual user accounts. Study monitor accounts should be created **before** facility accounts. During the establishment of a new facility account the facility's designated Study Monitor may then be selected from a drop-down menu, thereby effectively "linking" the facility with the appropriate Study Monitor. Pending review by the AADAP Office, each facility and Study Monitor will receive email notification with respect to the successful establishment of new user accounts.

[CHECK TO SEE IF YOUR FACILITY IS ALREADY ENROLLED](#)

figure 3.0



SELECT STUDY MONITOR FOR THIS FACILITY

Al Solonsky (Seattle, WA)

a

figure 4.0

3. **Selecting a Study Monitor** (figure 4.0): Your Study Monitor must already have an IPMS account established prior to the completion of Facility/Investigator accounts. While establishing your account, you will be required to select a (your) Study Monitor from a drop-down menu (a). Hence, your Study Monitor must be enrolled in the IPMS prior to the completion of your Facility/Investigator account enrollment.

YEAR	DRUG/INAD	SPECIES	NUMBER OF FISH TO BE TREATED
2012	Chloramine-T #9321	Mossambica Tilapia (<i>Oreochromis mossambicus</i>)	20000
2012	Oxytetracycline Hydrochloride #9033	Alabama Shad (<i>Alosa alabamae</i>)	2000000

+ ADD DRUG / INAD

SUBMIT FOR APPROVAL >>

figure 5.0

4. **Individual INAD Sign-Up** (figure 5.0): To complete Account Registration, Investigators must select the specific drugs/INADs that they are interested in using during the current calendar year. Instructions: 1) select the current calendar year; 2) select the drug/INAD that will be used; 3) select the fish species to be treated; 4) enter the estimated number of fish to be treated; and 5) click on the ADD DRUG/INAD button. If more than one fish species is to be treated under a specific DRUG/INAD, repeat the process (i.e., steps 1-5) for each species. Repeat the entire process for each drug/INAD that will be used.
5. **Submitting Account for Approval:** After all sign-up information has been entered, click on the "SUBMIT FOR APPROVAL" button (6). AADAP will review the provided account content, and when approved, you will receive email notification of account approval. If your account is not approved, you will receive email notification providing instructions on how to complete your account. Accounts will be reviewed within 2-3 business days of submitting the form.

Note: FDA and appropriate drug sponsors will be notified of each facility's drug/INAD participation. You may only use INAD drugs that you have selected. Should a facility desire to use another drug/INAD after the initial enrollment, new drugs/INADs can be added by clicking on the "Account Info" tab on the top menu bar.

6. **Billing Information:** By submitting this form, it is understood that if your facility is a non-federal facility, then a sign-up charge of \$400 per INAD will be invoiced to your facility. *Note: if 17 -Methyltestosterone Medicated Feed INAD is selected, then the sign-up charge is \$600.* Additionally, if a facility has not previously participated in the National INAD Program, a one-time start-up charge of \$100 will be included. Invoices will be mailed out upon completion and approval of Facility/Investigator accounts.
7. **Yearly Renewal of IPMS Accounts:** IPMS accounts will only be valid (active) for a single calendar year. At the beginning of each new calendar year, Facilities/Investigators should access their accounts and 1) update facility information, and most importantly 2) select the drugs/INADs that they wish to use in the upcoming calendar year. AADAP will send "reminder notifications" to all current IPMS participants in December notifying them of the need to update/re-activate their accounts.

C. Creating a Study Monitor Account

CREATE STUDY MONITOR ACCOUNT

ACCOUNT INFORMATION *Indicates Required Field

USER NAME*:

PASSWORD*:

Password requirements:

- Letters or numbers only
- At least 12 characters
- At least one upper-case character
- At least one lower-case character
- At least one number

CONFIRM PASSWORD*:

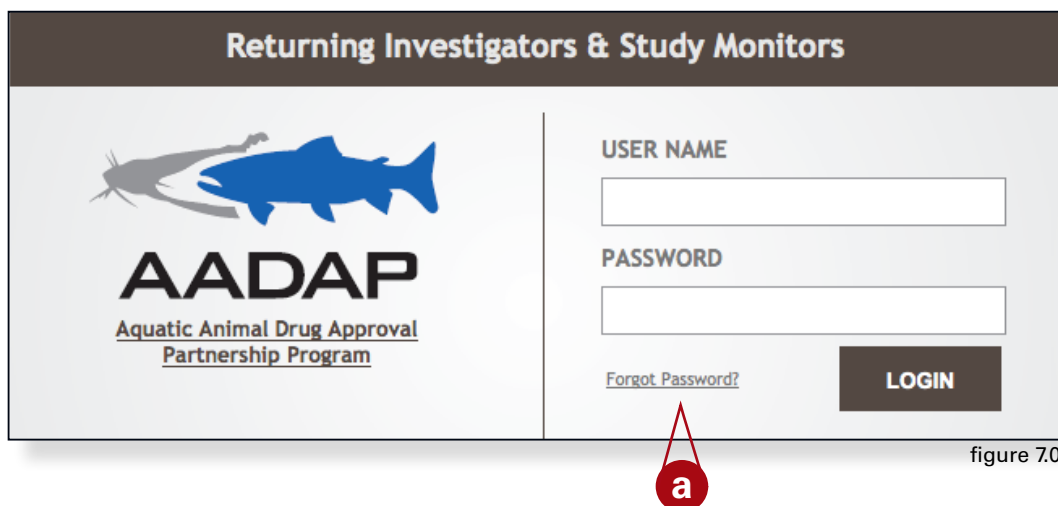
CONTACT NAME*:

EMAIL ADDRESS*:

figure 6.0 **SUBMIT FOR APPROVAL >>** **1**

1. **General Account Information** (figure 6.0): When generating an account each Study Monitor must provide all required information outlined in the Create Study Monitor Account form. User Names and Passwords must meet the standards as set forth by the Federal Government. Study Monitors must be enrolled in the IPMS before a Facility/Investigator can enroll in the system. *Note: the same email address cannot be used for both the Investigator's and the Study Monitor's accounts.*
2. **Submitting Account for Approval** (figure 6.0): After you have provided all required information, click on the "SUBMIT FOR APPROVAL" button (1). AADAP will review the provided account content, and when approved, you will receive email notification of account approval. If your account is not approved, you will receive email notification providing instructions on how to complete your account. Accounts will be reviewed within 2-3 business days of submitting the form.
3. **Yearly renewal of IPMS Accounts:** Study Monitor IPMS accounts do not need to be renewed on a yearly basis. These accounts will remain valid (active) until such time as the Study Monitor no longer wishes to participate. However, Study Monitors should "update" account information whenever appropriate.

3. Existing User Login



Returning Investigators & Study Monitors

AADAP
Aquatic Animal Drug Approval
Partnership Program

USER NAME

PASSWORD

[Forgot Password?](#) **LOGIN**

a

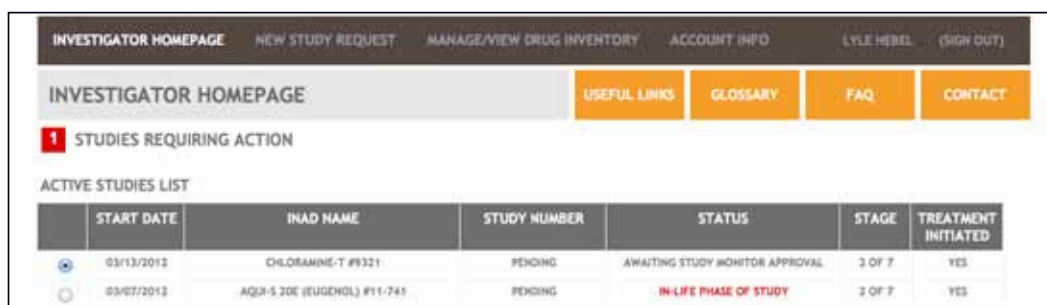
figure 7.0

- A. **Login** (figure 7.0): Both Investigators and Study Monitors use the same login area of the site, but each is directed to their appropriate homepage based on account-type. If you require any assistance with your account login, please contact AADAP (the National INAD Program Administrator).
- B. **Lost Password** (figure 7.0): Lost passwords may be retrieved by using the “Forgot Password” button (a) located below the sign-in form on the login page. Additionally, existing users can change their account password and edit other information from their homepage (see Account Information on page 9).

4. Basic IPMS Navigation from the Homepage

A. Investigator and Study Monitor Homepages

1. **General Navigation** (figure 8.0): Upon login, users will be taken directly to the appropriate homepage. Basic site navigation allows Investigators to create new studies, record new drug shipments, report study results, and complete a variety of other tasks. Basic site navigation allows Study Monitors to view, review, monitor, and approve or reject studies during the various stages of completion.



START DATE	INAD NAME	STUDY NUMBER	STATUS	STAGE	TREATMENT INITIATED
03/13/2012	CHLORAMINE-T #9321	PENDING	AWAITING STUDY MONITOR APPROVAL	3 OF 7	YES
03/07/2012	AQUA-S 200 (EUGENOL) #11-745	PENDING	IN-LIFE PHASE OF STUDY	2 OF 7	YES

figure 8.0

2. **Active Studies List** (figure 9.0): This table identifies any active studies currently in progress. Basic information about each study is defined, including study number, study status, and study stage. To view active studies, check the radio button (a) to the left of the start date of the study and click “View/Update Study.” (b) Provided below are the various study stages delineated in the active studies list:

Stage 1: New study initiated by investigator (Form W)

Stage 2: Study awaiting review and approval by Study Monitor

Stage 3: Study awaiting review and study number assignment by AADAP

Stage 4: In-life phase of study; treatment, data collection, and Results Report (Form 3)

Stage 5: Results Report (Form 3) awaiting review and approval by Study Monitor

Stage 6: Results Report (Form 3) awaiting review and approval by AADAP

Stage 7: Study complete

c

2 STUDIES REQUIRING ACTION

ACTIVE STUDIES LIST

	START DATE	INAD NAME	STUDY NUMBER	STATUS	STAGE	TREATMENT INITIATED
a	02/15/2012	AQUAFLOX (FLORFENOL)	123445	REJECTED BY AADAP	4 OF 7	YES
	02/15/2012	CHLORAMINE - T	78878	IN-LIFE PHASE OF STUDY	4 OF 7	YES
	02/15/2012	OXYTETRACYCLINE HYDROCHLORIDE	0228789	REJECTED BY MONITOR	4 OF 7	YES

d

b

VIEW/UPDATE STUDY >>

figure 9.0

3. **Studies Requiring Action** (figure 9.0): This notification (c) (located in the upper-left corner of the homepage) indicates that there are active studies requiring action. These actions are highlighted in red in the active studies list (d).
4. **Completed Studies List** (figure 10.0): This table displays all completed studies. Studies may be viewed and printed for archive purposes. To view completed studies, check the radio button to the left of the start date of the study and click “View Study.” (a) Additionally, after viewing study a 2-page summary report on the study may be viewed/printed by clicking on the “View/Print Report” button.

COMPLETED STUDIES

	START DATE	INAD NAME	STUDY NUMBER	STATUS	STAGE	TREATMENT INITIATED
a	03/13/2012	CHLORAMINE-T #9321	#12345	COMPLETED	7 OF 7	YES
	03/07/2012	AQUA-S 20E (EUGENOL) #11-741	#12349	COMPLETED	7 OF 7	YES

VIEW STUDY >>

figure 10.0

5. **Chemical Use Log “Snapshot” (Investigator homepage only)** (figure 11.0): At the bottom of the Investigator homepage, and for each drug/INAD for which you have signed-up, there is a short summary of amount of drug on-hand.

CHEMICAL USE LOG - FORM 2

DATE RECEIVED	DRUG / INAD	DRUG LOT NUMBER	AMOUNT ON-HAND
02/15/2012	CHLORAMINE-T #9321	12345	2000

figure 11.0

6. **Facility List (Study Monitor homepage only):** By clicking on the “Facility List” tab located on the top menu bar, Study Monitors will be provided a list (including contact information) of all facilities/Investigators they are currently monitoring. While inside the facility list, Study Monitors will also be able to view the Chemical Use Log (Form 2) and Drug Receipt Form (Form 1) of any facility they are monitoring.

7. **Account Information** (figure 12.0): By clicking on the “Account Info” tab (a) located in the top menu bar you may make any needed changes to your enrollment (e.g, contact information, password reset, etc.). Note: Investigators should also use this site if they need to add additional drugs/INADs to their existing enrollment.
8. **Useful Links** (figure 12.0): By clicking the “Useful Links” tab (b) located on the top menu bar, you will find a number of links that should assist you throughout the INAD/IPMS process. Examples include direct links to individual INAD study protocols, drug fact sheets, AFS Treatment Calculator, AADAP’s Approved Drugs for Use in Aquaculture Desk Reference Guide, etc.
9. **Glossary** (figure 12.0): By clicking on the “Glossary” tab (c) located on the top menu bar you will find a general glossary of INAD/IPMS-related terminology. These terms will assist you as you navigate throughout the IPMS.
10. **FAQs** (figure 12.0): By clicking of the “FAQ” tab (d) located on the top menu bar you will find general information that will hopefully assist you when completing studies and navigating throughout the IPMS. If you don’t find to the answer to you question, please contact AADAP. Please don’t be shy, your questions will be added to this site and over time will help us to help others.
11. **Contact Information** (figure 12.0): By clicking on the “Contact” tab (e) on the top menu bar all participants will find the contact information for AADAP. Please do not hesitate to contact AADAP for assistance. Investigators will also be provided contact information for their Study Monitors. Note: Study Monitors can access contact information for their investigators via the “Facilities List” as described above.

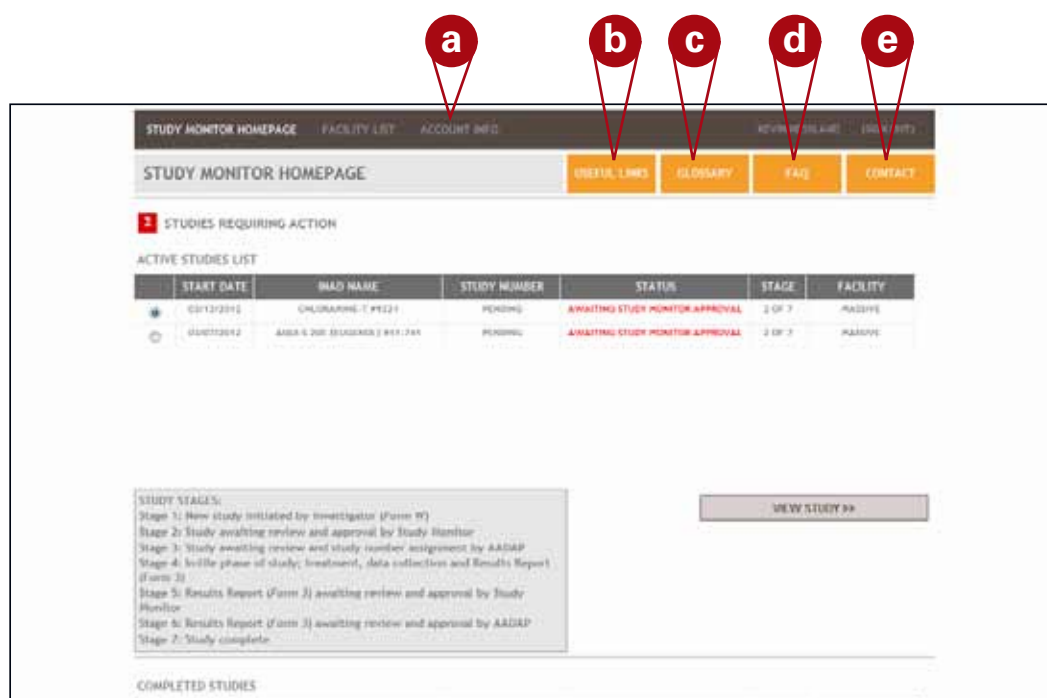


figure 12.0

5. Managing Drug Inventory - Drug Receipt (Form 1) & Chemical Use Log (Form 2)

figure 13.0

A. Drug Receipt – Form 1 (figure 13.0)

1. **Recording a New Drug:** Each time a new drug shipment is received, it must immediately be logged into the IPMS by completing a new Drug Receipt Form (Form 1). New drug shipments are recorded into the system through the “Manage/View Drug Inventory” tab (a) on the top menu bar. All required drug receipt information is recorded into the system through defined fields in the Drug Receipt Form. Click on the “Receipt of Drug” button (b) to access Form – 1. Once all information has been entered, click on the “Add to Drug Inventory” button located at the bottom of the page. At this time an email will be sent to both the Study Monitor and AADAP notifying them of drug receipt.

IMPORTANT: Once a Drug Receipt Form has been completed and added to drug inventory, NO changes can be made to it.

2. **Drug Lot Number Information:** For a given drug, there is a chance that Investigators will receive multiple drug shipments with the same drug lot number. Each Drug Receipt entry is cataloged by date received, which allows for multiple shipments of the same drug to be recorded with the same drug lot numbers. Once the Drug Receipt Form is completed, drug inventory can be viewed in the Chemical Use Log.

B. Chemical Use Log – Form 2 (figure 13.0)

1. **General Information:** The Chemical Use Log (Form 2) is accessed via the “Manage/View Drug Inventory” tab (a) on the top menu bar. The Chemical Use Log tracks the inventory of all INAD drugs and displays a quick overview of drug information, including drug lot number and amount on hand. The Chemical Use Log (c) is automatically populated from information entered in the Receipt of Drug (Form 1), and automatically “balanced” based on actual drug use as reported in the Results Reports (Form 3s). The Chemical Use table is a detailed record of all activity for a specific drug/INAD. If any unused drug is transferred to another facility or disposed of, it must be recorded “manually” as described in “3 and 4” below.
2. **Drug Receipts:** Click on the “View Drug Receipts” (d) button to review the details of a drug shipment’s previously received.
3. **Drug Transfers:** Click on the “Transfer” (e) button to document the transfer of drug inventory to another authorized facility.
4. **Drug Discards:** Click on the “Discard” (f) button to document the disposal of drug inventory according to guidelines provided in the Study Protocol.

6. Getting Ready to Initiate a Treatment/study – Study Stages 1 - 3

figure 14.0

A. Stage 1 - New Study Initiated by Investigator (Form W) (figure 14.0)

1. **Form W Study Worksheet:** To initiate a new study click on the “New Study Request” (a) tab located on the top menu bar. This action will take you to the New Study Request – Form W Study Worksheet page. Select the appropriate drug/INAD at the top of the page (b), and then proceed to entering all requested information under Treatment Information and Schedule. Although it is acknowledged that some of the requested information may be “pre-study estimates,” please be as accurate as possible and note that this information will be used to automatically populate portions of the Results Report (Form 3) during Stage 4. Also note that although you do not need to have INAD drug on hand to complete/submit a Form W, you must have completed a Drug Receipt (Form 1) and Chemical Use Log (Form 2) before proceeding to Stage 4.
2. **Treatment Information and Schedule:** As described above, the Treatment Information and Schedule defines the proposed treatment. The majority of requested information is identical for all drugs/INADs (i.e., top of page; estimated amount of drug needed for treatment thru study design). However, it should be noted that towards the bottom of the page under Drug Specific Elements differences in requested information do exist between specific drugs/INADs, and that these differences (drug specific elements) have been necessitated by drug/INAD “use-pattern.” The identified use-patterns include 1) immersion drugs, 2) medicated-feeds, 3) spawning hormones, 4) anesthetic drugs, 5) immersion marking drugs, and 6) MT medicated-feed. Within these 6 groupings the information requested is identical.
3. **Submit for Approval:** When all requested information has been entered into Form W click on the “Submit for Approval” (c) button located at the bottom of the page. If the form is incomplete, you will be returned to the form and missing information will be highlighted in red. Once a Form W has been successfully submitted 1) the Investigator will be returned to the homepage, and 2) the Study Monitor will immediately be sent an email notifying them that a Form W is awaiting their attention.

Note: Study Worksheets (Form Ws) cannot be saved in an incomplete state for completion at a later date. Once initiated, a Study Worksheet (Form W) must be completed and submitted or all data will be lost (i.e., a new Study Worksheet (Form W) will need to be initiated at a later date).

B. Stage 2 – Study awaiting review and approval by Study Monitor

1. **Study Monitor Approval Status:** In this stage, the Study Monitor reviews the Study Worksheet (Form W) for appropriate content and information. The need for review and approval will be indicated by red highlighting in the Active Studies List, and to view/review the Study Worksheet (Form W) the Study Monitor should check the radio button to the left of the start date of the study and click “View Study.”
2. **Study Monitor Approval:** To approve the Study Worksheet (Form W), the Study Monitor should click on the “Approve for Testing” button at the bottom of the page. When a Form W has been approved 1) the Study Monitor will be returned to the homepage, and 2) emails will automatically be sent to both the Investigator and AADAP notifying them of this action. The study will also immediately advance to Stage 3 – Study awaiting review and study number assignment by AADAP.
3. **Study Monitor Rejection:** To reject the Study Worksheet (Form W), the Study Monitor should click on the “Reject for Testing” button at the bottom of the page. If the Study Monitor rejects the study, a window labeled “Rejection Note” will pop-up and allow the Study Monitor to explain the reason(s) for rejection. An email notice will automatically be sent to the Investigator notifying them that the Study Worksheet (Form W) has been rejected, and will include the reason(s) for rejection. Investigators should make the proper adjustments and resubmit the Study Worksheet (Form W) to the Study Monitor for approval.

Note: *As a result of Study Worksheet (Form W) rejection, the “study status” on both the Investigators and Study Monitors Active Study List will be highlighted green to delineate a rejection.*

C. Stage 3 – Study awaiting review and study number assignment by AADAP

1. **Study Number:** Based on information provided in the Study Worksheet (Form W) AADAP will assign each study a unique study number. The study number will be use to track the study within the IPMS all the way through until study completion (Stage 7). The study number will automatically be populated on all further forms, submissions, and correspondence relating to the study
2. **AADAP Approval:** AADAP reviews the Study Worksheet for appropriate content and information. If AADAP approves the study, emails will automatically be sent to both the Investigator and Study Monitor notifying them of study approval and study number. The study will also immediately advance to Stage 4 – In-life phase of study, treatment, data collection, and Results Report (Form 3).
3. **AADAP Rejection:** If AADAP rejects the study, email notification that includes the reason for rejection will immediately be sent to both the Investigator and Study Monitor. For all practical purposes, this action will return the study to Stage 1. Investigators will need to make the proper adjustments to the Study Worksheet (Form W) and resubmit to the Study Monitor for approval; Study Monitors will need to review/approve and resubmit to AADAP for approval and study number.

Note: *As a result of Study Worksheet (Form W) rejection, the “study status” on both the Investigators and Study Monitors Active Study List will be highlighted green to delineate a rejection*

7. Treatment and Study Reporting – Study Stages 4 - 7

A. Stage 4 - In-Life Phase of study, treatment, data collection, and Results Report (Form 3) (figure 15.0)

INVESTIGATOR HOMEPAGE NEW STUDY REQUEST MANAGE/VIEW DRUG INVENTORY ACCOUNT INFO LYLE HEBEL (SIGN OUT)

INVESTIGATOR HOMEPAGE USEFUL LINKS GLOSSARY FAQ CONTACT

2 STUDIES REQUIRING ACTION

ACTIVE STUDIES LIST

	START DATE	INAD NAME	STUDY NUMBER	STATUS	STAGE	TREATMENT INITIATED
<input type="radio"/> a	02/15/2012	AQUAFLOX (FLORFENOL)	123443	REJECTED BY ADDAP	4 OF 7	YES
<input type="radio"/>	02/15/2013	CHLORAMINE - T	78878	IN LIFE PHASE		

figure 15.0

VIEW/UPDATE STUDY >> b

1. **In-life Phase:** During the In-life phase of the study (*stage 4*) treatment is administered and data collected throughout the entire study period (i.e., pretreatment, treatment, and posttreatment periods). Both treatment and data collection should be conducted according to parameters outlined in the INAD Study Protocol.

Note: Prior to initiating treatment, Investigators are encouraged to view and print a Results Report (Form 3) to be sure that they are fully aware of all treatment and data collection parameters. Results Report (Form 3s) are accessed as described immediately below. Important: Do not attempt to enter any data into the form at this time; simply view, print, and exit the page.

2. **Results Report (Form 3):** All pertinent information regarding a study is reported on the Results Report (Form 3) under Treatment Information and Schedule. To access this form, from the Active Studies List check the radio button (a) to the left of the start date of any Stage 4 study and click “View/Update Study” (b). All fields shown must be completed. Although a number of fields will already be populated based on information entered into the Study Worksheet (Form W), all fields should be updated/completed to reflect actual study data.

The majority of requested information is identical for all drugs/INADs (i.e., top of page; amount of drug used thru average water quality parameter during treatment). However, it should be noted that towards the bottom of the page under Drug Specific Elements differences in requested information do exist between specific drugs/INADs, and that these differences (drug specific elements) have been necessitated by drug/INAD “use-pattern.” The identified use-patterns include 1) immersion drugs, 2) medicated-feeds, 3) spawning hormones, 4) anesthetic drugs, 5) immersion marking drugs, and 6) MT medicated-feed. Within these 6 groupings the information requested is identical.

Note: In order to complete a Results Report (Form 3) you must have completed a Drug Receipt (Form 1) and Chemical Use Log (Form 2).

3. **Editing/Saving Results Report (Form 3)** (*figure 16.0*): As studies progress through the In-life phase, Investigators may choose to update data records intermittently in Results Report (Form 3) as new data becomes available (as compared to waiting until completion of the entire study period before entering all data). There are two types of “Save” buttons located at the bottom of the page: 1) Save Only; and 2) Save/Submit for Approval. To intermittently enter and save data during the In-life phase, be sure to click on the “Save Only” button (1).

Note: All required fields must be filled out in order to save any new or edited study data. You may use a zero (i.e., “0”) as place-holders in these fields until you have collected the required data. Under the “Treatment Record” section of Form 3 (e.g., mortality record, spawning record, marking record, etc.) you only need to include a single data entry (i.e. data for a single date). If all required fields have not been filled out correctly, you will receive a red error message notifying you of missing data. Conversely, a green message will notify you that data was successfully saved.



figure 16.0

4. **Saving/Submitting Results Report (Form 3):** When all requested information under “Treatment Information and Schedule” has been entered, click on the “Save/Submit for Approval” button (2) located at the bottom of the page. If the form is incomplete, you will be returned to the form and missing information will be highlighted in red. Once a Results Report (Form 3) has been successfully submitted 1) the Investigator will be returned to the homepage, and 2) the Study Monitor will immediately be sent an email notifying them that a Form 3 is awaiting their attention.
5. **Treatment not initiated** (*figure 17.0*): If an Investigator decides not to conduct a study after a Study Number has been assigned, they should simply click the “No” (a) radio button next to the “Was Treatment Initiated?” line (located at the very top of the page above “Treatment Information and Schedule”), and enter a reason why the study was not conducted. The Investigator should then click on the “Save/Submit for Approval” (2) button and the study will immediately be moved to the Completed Studies table on the Investigator and Study Monitor homepages. “Treatment not initiated” studies cannot be reinitiated after termination.



figure 17.0

6. **Study Duplication (Creating a new Form W)** (*figure 18.0*): By clicking on the “Duplicate this Study” (a) button (located immediately below Worker Safety Considerations check box), Investigators can create/initiate a new Form W that will be populated with “Treatment Information and Schedule” information from the current study. Only the information above the “Duplicate this Study” button will be duplicated (transferred) to the new Form W. The drug-specific data elements will not be duplicated. The Duplicate this Study feature is designed to makes it easier for Investigators that perform repetitive studies with a similar “Treatment Information and Schedule” to initiate new studies. Investigators may also access this feature via the “Completed Studies List” on their homepage.



figure 18.0

B. Stage 5 - Results Report (Form 3) awaiting review and approval by Study Monitor

1. **Study Monitor Approval Status:** In this stage, the Study Monitor reviews the Results Report (Form 3) for appropriate content and information. The need for review and approval will be indicated by red highlighting in the Active Studies List, and to view/review the Results Report (Form 3) the Study Monitor should check the radio button to the left of the start date of the study and click "View Study."
2. **Study Monitor Approval:** To approve the Results Report (Form 3), the Study Monitor should click on the "Approve Study" button at the bottom of the page. When a Form 3 has been approved 1) the Study Monitor will be returned to the homepage, and 2) emails will automatically be sent to both the Investigator and AADAP notifying them of this action. The study will also immediately advance to Stage 6 – Results Report (Form 3) awaiting review and approval by AADAP.
3. **Study Monitor Rejection:** To reject the Results Report (Form 3), the Study Monitor should click on the "Reject Study" button at the bottom of the page. If the Study Monitor rejects the study, a window labeled "Rejection Note" will pop-up and allow the Study Monitor to explain the reason(s) for rejection. An email notice will automatically be sent to the Investigator notifying them that the Results Report (Form 3) has been rejected, and will include the reason(s) for rejection. Investigators should make the proper adjustments and resubmit the Results Report (Form 3) to the Study Monitor for approval.

C. Stage 6 – Results Report (Form 3) awaiting review and approval by AADAP

1. **AADAP Approval:** AADAP reviews the Results Report (Form 3) for appropriate content and information. If AADAP approves the study, emails will automatically be sent to both the Investigator and Study Monitor notifying them of study approval. The study will also immediately advance to Stage 7 – Study Complete.
2. **AADAP Rejection:** If AADAP rejects the Results Report (Form 3), email notification that includes the reason for rejection will immediately be sent to both the Investigator and Study Monitor. For all practical purposes, this action will return the study to Stage 4. Investigators will need to make the proper adjustments to the Results Report (Form 3) and resubmit to the Study Monitor for approval; Study Monitors will need to review/approve and resubmit to AADAP for final approval.

D. Stage 7 – Study Complete

1. **No further action required:** Stage 7 indicates that the study has been completed and no further action is required. The study is automatically moved from the "Active Studies List" to the "Completed Studies List" on both Investigator and Study Monitor hompages. Studies may be viewed and printed for archive purposes. To view completed studies, check the radio button to the left of the start date of the study and click "View Study." Additionally, a 2-page summary report on the study may be viewed/printed by clicking on the "View/Print Report" button.
2. **Completed Studies Life-Span:** Completed studies will remain in the Completed Studies List for the life-span of the Study Monitor and Investigator/Facility IPMS accounts.